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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,271	10/09/2003	Jeffrey W. Leon	86363SLP	8270

70523 7590 01/23/2008
Carestream Health Inc,
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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
01/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/682,271	Applicant(s) LEON ET AL.	
	Examiner T. D. Wessendorf	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 30 October 2007.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-69 is/are pending in the application.

4a) Of the above claim(s) 2-11,13-33 and 37-69 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1, 12 and 34-36 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-69 are pending.

Claims 2-11, 13-33 and 37-69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 1, 12 and 34-36 are under consideration.

Withdrawn Rejection

In view of the amendments to the claims and applicants arguments the 35 U.S.C. 112, second paragraph, rejection has been withdrawn. Also, in view of the terminal disclaimer of record and 131 declaration, the obviousness double patenting and the 35 USC 103 rejections over Qiao et al and over Murphy or Marchina are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 12 and 34-36, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection).

Claim 1 which recites "filler does not absorb light" and "the filler is homogenously disbursed in said gelatin" is not supported in the as-filed specification. MPEP 714.02 clearly states that applicants point out where in the specification support for the new claim limitation appears.

Claim Rejections - 35 USC § 102

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

a) A patent may not be obtained though the invention is not identically disclosed or as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 12 and 34-36, as amended, are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Anderson et al(USP 7179638).

Anderson et al discloses at e.g., claim 6:

> A microarray comprising a solid phase support and at least about 500 cells per square centimeter wherein each cell contains an agent of interest that is not chemically bound to the solid phase support and a plurality of structures (filler and gelatin) bound to said solid phase support, wherein each of a plurality of structures has an immobilized agent of interest(functional groups, as claimed) available for binding to a target, wherein the target is a binding partner for the agent of interest, and wherein the microarray contains a plurality of different agents of interest in a corresponding plurality of different structures, wherein each of the structure forms a hollow chamber with the agent of interest immobilized on an inner surface of the hollow chamber.

Anderson discloses the various components comprised in the microarray at .g., col. 5, line 60 up to col. 11, line 37

In a still further aspect, the invention relates to the incorporation of a **non-fluorescent dye** or other light absorbing material in the substance of the array to control the depth to which light used to excite fluorescence penetrates the array, thereby controlling the depth to which fluorescence analytes are detected, and insuring that fluorescent analytes which diffuse too deeply into the content of the cells, and therefore do not diffuse out, are not detected.

The term "particle" includes a large number of insoluble materials of any configuration…. Examples include silica, cellulose, Sepharose beads, polystyrene (solid, porous and derivitized) beads, controlled-pore glass, gel beads, sols, biological cells, subcellular particles, microorganisms (protozoans, bacteria, yeast, viruses, etc.) micelles, liposomes, cyclodextrins, two phase systems (e.g. agarose beads in wax) etc. and other structures which entrap or encapsulate a material. Particularly preferred are recombinant hosts and viruses that express the protein of interest. Even certain high molecular weight materials, such as, polymers and complexes, may serve as immobilizing structures that would constitute a "particle".

> The terms "arrays" and "microarrays" are used somewhat interchangeably differing only in general size. The instant invention involves the same methods for making and using either. Each array typically contains many cells (typically 100 1,000,000+) wherein each cell is at a known location and contains a specific component of interest. Each array therefore contains numerous different components of interest.

In a related aspect, "device" is used to describe both arrays and microarrays, where the array or microarray may comprise other defined components including surfaces and points of contact between reagents.

Further, "substrate" is also a term used to describe surfaces as well as solid phases which may comprise the array, microarray or device.

A fifth class of fibers is comprised of hollow impermeable tubules typically formed from plastics including, but not limited to, polyethylene, polypropylene, Teflon.RTM. or polyvinyl chloride, and is filled completely with a gel or other polymerizing material to which agents of interest are attached directly. The external surfaces of the tubes may be modified chemically or physically to accept adhesives used to bind the bundled tubes together. The internal surface also may be modified so that the gel or polymerizing mixture introduced into the tubes will adhere, preferably by covalent attachment. Acrylamide derivatives may be linked to the wall to make an acrylamide gel adhere, while ***gelatin,*** agar, or agarose derivatives may be attached similarly to link with the respective gels. Methods for linking agents of interest, such as, proteins and nucleic acids, to linear acrylamide, ***gelatin*** and agarose are well known, and the derivatized molecules can be incorporated into the gels used for casting. Acrylamide can be made to gel at room temperature either chemically or using photoactivation, while low temperature-gelling Sepharose is available. ***Gelatin*** sets slowly and at temperatures below ambient. The **polymers used to fill the tubes are typically homogeneous, but may contain agents of interest,**

which become attached to the polymerizing medium. Examples include covalent attachment of proteins to short acrylamide chains that become incorporated into acrylamide gels and proteins covalently linked to *gelatin*. Thus, gels are available or can be produced which contain labile biomolecules without exposing them to denaturing temperatures. The structure of such tubes is illustrated in FIG. 3 where tube 16 is filled with a cross-linked gel 17 to which are attached agents of interest 18. A side view 19 and end view 21 of a sectioned tube illustrates the availability of immobilized agents 21. (Emphasis added).

Accordingly, the claimed biological microarray comprising of the broad aimed components are met or obvious over the biological microarray of derson, which discloses all the claimed elements of the claimed ological microarray.

Response to Arguments

Applicants assert that Anderson fails to disclose functional compounds affixed in the gelatin. See column 8, lines 51-55 of Anderson, which states: An element of a microarray is formed by performing a polymeric strand, then incorporating a biological target molecule into the strand by a method including, but not limited to, diffusion from a solution containing the biological target molecule. Anderson produces polymeric strands and thereafter soaks the strands in a solution that contains a functional compound. In this manner, functional compounds are coated onto the surface of the polymeric strand. The functional compound is not disposed within the gelatin itself.

In response, applicants' argument with respect to the method by which the microarray of Anderson is formed is not commensurate in scope with the claims. The claims are directed to a microarray, per se and not to any method. Thus, as recognized by applicants Anderson teaches the same components of the array except that the functional compound is coated onto the surface instead of disposed, as claimed and argued. However, the form/manner to which the functional group is attached to the gelatin does not make the compound, microarray different. The specification defines affixed at paragraph [0073]:

> By "affixed" it is meant that the precursor polymer is applied to the gelatin surface and adheres to the gelatin by any of a number of chemical and physical attractive mechanisms including ionic interactions, covalent bonds, coordinative bonds, hydrogen bonds, and Van-der-Waals interactions. For example, a dehydrating agent such as a carbodiimide, a pyridyl dication ether, or a carbamoylpyridinium compound may be used to bind an amine-containing polymer or a carboxylic acid-containing polymer to a gelatin surface via amide bonds. Similarly, a bis(vinylsulfonyl) compound may be used to bind poly(ethyleneimine) to a gelatin surface.

Applicants further argue that Anderson also discloses light absorbing material that diminishes the fluorescence of analytes. Such a light absorbing material cannot fairly be considered a filler compound. The light absorbing materials of Anderson specifically absorb light, including; the light emitted by the captured molecule when such molecule undergoes fluorescence. Such light absorbing materials are clearly not fillers. The filler materials disclosed in the specification do not absorb light. At best, when such particles are large, the particles might scatter, but not absorb, light. Moreover, the light absorbing materials of Anderson are not homogenously disbursed in a gelatin. See column 29, lines 34-52.

In response, attention is drawn to Anderson above at e.g., col. 5 which recite non-fluorescent dye. Furthermore, as stated above the claimed filler that does not absorb light is not supported in the as-filed specification. Be it as it may, whether the filler of Anderson is a non-absorbent light is immaterial as the filler is the same if not similar to that as claimed.

No claim is allowed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Maher (6969449) discloses a Multi-well plate and electrode assemblies for ion channel assays.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 2-11, 13-33 and 37-69 drawn to an invention nonelected. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The xaminer can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0765. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. W
T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
January 16, 2008